IMPACT INNOVATION OF MEDICAL DEVICES TO SERVE LOW-INCOME PATIENTS

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Table of Contents

3  Executive Summary
5  Introduction
7  Reverse, Frugal, and Impact Innovation
10 The Rarity of Reverse, Frugal, and Impact Innovations for Medical Devices
12 Design and Dissemination Processes in Reverse, Frugal, and Impact Innovation
12  Vscan: A Portable Ultrasound for the Whole World
14  GOGRII: An Off-Road Indian Wheelchair and a High-End U.S. Mountain Bike
16  Embrace: A Low-Income Country Infant Warmer and a U.S. Baby Sleeping Bag
18  D-Rev: A Prosthetic Knee for Amputees in Low-Income Countries
21 Whom Do Reverse, Frugal, and Impact Innovations Benefit?
23 Impact Innovation for Medical Products: Opportunities and Challenges
25 References
Executive Summary

Over the past five years, the terms reverse and frugal innovation have been embraced by health sector professionals looking for ways to advance the public good through market-driven or customer-centric mechanisms. Reverse innovation is the phenomenon by which products and services initially intended for low-income countries spread to high-income countries; frugal innovation is the process of reducing the complexity and cost of technologies or delivery models in order to sell them to overlooked customers. There are currently dozens of examples of reverse and frugal innovation for health care services, such as low-cost hospital networks and preventative health care models. Less is known, however, about medical products that have moved from low-to high-income markets or from one low-income country to another. Closing this information gap is critical for those trying to reduce health inequities among the world’s poorest by increasing access to much-needed medical devices. It is also critical for those trying to sustainably fund world-class healthcare products for the poor.

At D-Rev, we are investigating whether a medical device that is sold in low-income countries and successfully creates impact could also close health inequities in the United States. We researched reverse and frugal innovation and explored three questions:

1. How prevalent are medical devices that are identified as reverse and frugal innovations?

2. What can be learned from the health technologies that have transferred “back” to U.S. markets? Specifically, what do entrepreneurs, investors, donors, designers, and students need to think about for a successful impact innovation market entry in the U.S.?

3. What can donors, private companies, and nongovernmental organizations (NGOs) do to support the development and dissemination of high impact medical devices for low-income users?

We found that the total number of successful reverse and frugal innovations for medical devices is quite small. That may be because the phenomenon of this kind of innovation is fairly new or because health products have specific barriers to market entry and scale.
We additionally found that reverse innovation of low-cost medical devices is not only rare—it is often misunderstood. Ironically, the terms reverse and frugal innovation somewhat restrict the goal of bringing medical devices sold in low-income countries to high-income nations. Reverse innovations, when available for sale in high-income countries, often cost too much to be available for patients living in poverty.

Frugal innovation can imply that low-cost products do not need to be of the highest quality, limiting their ability to scale. For these reasons, we introduce a new term that is more targeted in terms of achieving social equity goals: “impact innovation.” Impact innovation is the process by which products and services are specifically designed and disseminated to close social equity gaps among the world’s poor.

We believe there is potential for impact innovations to be transferred within low-income countries and to high-income countries thus closing health inequities for the world’s poor. We provide an accompanying framework for creating impact innovation for medical devices. This impact innovation framework serves as a preliminary guide for entrepreneurs, investors, donors, designers, and students looking to enter the U.S. market with a health technology that has proved successful in other markets, particularly those serving low-income patients. We also hope the paper and framework contribute to ongoing efforts to better understand the distinct challenges companies and organizations face when trying to close health inequities through much-needed medical devices.
Introduction

Around 2009, two terms came into parlance among business scholars and entrepreneurs interested in innovation and emerging markets. Those terms, “reverse innovation”—the phenomenon by which products and services initially intended for low-income countries spread to high-income countries—and “frugal innovation”—the process of reducing the complexity and cost of technologies or delivery models in order to sell them to overlooked customers—have now been embraced by health sector professionals looking for ways to advance the public good through market-driven or customer-centric mechanisms.

It is now quite common, for example, for global health professionals to peruse articles like Thomas Bollyky’s “New, Cheap, and Improved: Assessing the Promise of Reverse and Frugal Innovation to Address Noncommunicable Diseases” or “Realigning Health With Care,” an article by Rebecca Onie, Paul Farmer, and Heidi Behforouz about health care delivery models from the global south that can improve global north patient outcomes while cutting costs. Indeed, there are an increasing number of interesting examples of frugal innovations in the delivery of health services and systems. Bollyky writes about Aravind Eye Care, an Indian hospital network that performs 60 percent as many eye surgeries as the United Kingdom’s National Health Service at one one-thousandth of the cost, due to its standardized care process. And Onie, Farmer, and Behforouz write about Associação Saúde Criança, a social innovation in Brazil that sends low-income children home after hospitalizations with resources for ongoing nutrition, sanitation, and psychological support—a service that is similar to Onie’s nonprofit Health Leads, which connects low-income American hospital patients to an array of social services like food and free clothing.

There are also several U.S. universities that are exploring frugal innovations in the health care sector. UCLA’s Global Lab for Health, for example, is assembling a database of innovations in healthcare delivery “to support the marketing and dissemination of service delivery innovations, and to provide user reports that will encourage potential adopters to take the next steps.” As of October 2015, 85 innovations have been crowd-sourced and posted.

4 UCLA Global Lab for Health website: http://www.globallabforhealth.org/
There is less analysis, however, of medical products that have moved from low- to high-income markets—or from one low-income country to another. Closing this information gap is critical for those trying to reduce health inequities among the world’s poorest by increasing access to much-needed medical devices. It is also critical for those trying to sustainably fund world-class healthcare products for the poor.

Ironically, the terms reverse and frugal innovation somewhat restrict both goals. This paper documents that reverse innovation of low-cost medical devices is not only rare—it is also often misunderstood. Our research finds that reverse innovations, when available for sale in high-income countries, often cost too much to be available for patients living in poverty.

Likewise, frugal innovation can imply that low-cost products do not need to be of the highest quality, limiting their ability to scale. For these reasons, we introduce a new term that is more targeted in terms of achieving social equity goals: “impact innovation.” We also provide an accompanying framework for creating impact innovation for medical devices.

*Impact innovation is the process by which products and services are specifically designed and disseminated to close social equity gaps among the world's poor.* At D-Rev, we practice impact innovation by designing and delivering medical technologies to close the quality health care gap for under-served populations. As such, we have been seeking to understand whether a medical device that we successfully sell and have impact with in low-income countries could also close health inequities in the U.S.

This quest has led us to research reverse and frugal innovation and to explore three practical questions regarding innovation for low-income medical devices:

1. How prevalent are medical devices that are identified as reverse and frugal innovations?
2. What can be learned from the health technologies that have transferred “back” to U.S. markets? Specifically, what do entrepreneurs, investors, donors, designers, and students need to think about for a successful impact innovation market entry in the U.S.?
3. What can donors, private companies, and nongovernmental organizations (NGOs) do to support the development and dissemination of high impact medical devices for low-income users?
We have answered these questions by:

1. Exploring how reverse and frugal innovations have been defined and understood, and how successful these innovations have been in bringing needed health technologies to American patients.

2. Questioning why reverse innovation for medical devices is rare by examining one fully realized reverse innovation by one of the world’s largest multinational companies and three examples of innovations developed by small product companies.

3. Providing an impact innovation framework that can serve as a preliminary guide for entrepreneurs, investors, donors, designers, and students looking to enter the U.S. market with a health technology that has proved successful in other markets, particularly those serving low-income patients.

Our belief is that this analysis will contribute to the ongoing efforts to better understand the distinct challenges companies and organizations face when trying to close health inequities through much-needed medical devices.

**Reverse, Frugal, and Impact Innovation**

Over the past few years, frugal and reverse innovations have become lauded development approaches in an era of rising economic interdependency, huge leaps in technological innovation, and a quest to alleviate poverty through market-based solutions.

The two terms have multiple ideological roots, which is part of the reason they are often used interchangeably. Among these roots are the appropriate technology movement of the 1950s and the works of British economist E.F. Schumacher’s 1973 book *Small Is Beautiful: Economics as if People Mattered* and American business professor C. K. Prahalad’s 2004 book *Fortune at the Bottom of the Pyramid: Eradicating Poverty through Profits*. Also of importance to the understanding of the two terms is a wide variety of innovation scholarship, including Clayton Christensen’s 1997 book *The Innovator’s Dilemma*. 
Dartmouth Business Professor Vijay Govindarajan coined and was the first to describe reverse innovation in a October 2009 Harvard Business Review article entitled “How GE Is Disrupting Itself,” co-authored by General Electric CEO Jeffrey Immelt and business consultant Chris Trimble. The article introduced reverse innovation as the process whereby goods developed as inexpensive models to meet the needs of low-income nations, such as battery-operated medical instruments in countries with limited infrastructure, are then repackaged as low-cost innovative goods for Western buyers. The authors argue that reverse innovation is the opposite of “glocalization”—the process by which Western companies develop products for their home markets and then distribute them worldwide, with some adaptations to local conditions. What is key to reverse innovation, they said, is investigating, understanding, and serving local markets with goods and services specifically tailored to local consumers’ needs.

Frugal innovation is similar in meaning and application to reverse innovation. Over the past five years the two terms have been used interchangeably by scholars, practitioners, governmental and nongovernmental representatives, and funders, along with the terms trickle-up innovation, boomerang innovation, and constraint-based innovation. Frugal innovation is usually defined as taking the needs of poor consumers as a starting point and working backwards, while stripping the products down to their bare essentials to reduce costs. Popular examples include Tata Motors $2,200 car, the Nano; Godrej & Boyce Manufacturing’s $70 refrigerator, which runs on batteries; Jaipur leg, a low-cost prosthesis, which D-Rev advanced through its ReMotion Knee; and mobile banking solutions like Safaricom’s M-Pesa.

As with reverse innovation, frugal innovation first was viewed as a business strategy for for-profit companies, usually multinational ones. Navi Radjou and his coauthors Jaideep Pabhu and Simone Ahuja helped popularize the term in their 2012 book Jugaad Innovation: Think Frugal, Be Flexible, Generate Breakthrough Growth and in the 2015 book Frugal Innovation: How To Do More With Less. In both books, the authors argue that the idea of jugaad (a Hindi word meaning an improvised solution born from ingenuity and cleverness) is leading to dramatic changes for companies around the world. Their focus is less the social impact of frugal innovation for customers as the market share and financial return for companies.

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In Kenya, there is a similar concept, jua kali, meaning “fierce sun” in Swahili for the artisan entrepreneurs who work by the side of the road.
Companies and business strategists are not the only constituents interested in reverse and frugal innovation. Increasingly, social entrepreneurs, international development practitioners, funders, and university scholars have found the term useful in thinking about how to adapt, improve, and combine new approaches to lower the cost and increase the accessibility of products and services globally. That interest has grown because market-based solutions can reveal whether a product or service is really wanted by or useful to low-income people—and can define whether that product or service should continue to be available.

In essence, reverse and frugal innovation offer an alternative to the donation and subsidization culture that has long defined international development. These approaches show the power of business solutions to more efficiently address civil society and government problems. But because the terms have been developed and embraced largely by business scholars and strategists, reverse and frugal innovation—by definition—do not emphasize social impact for low-income populations. For this reason, we introduce the term “impact innovation” and provide an accompanying framework that focuses on reducing social inequities for low-income patients. By definition: Impact innovation is the process by which products and services are specifically designed and disseminated to close social equity gaps among the world’s poor.

Impact innovation uses principles similar to design organizations. Those principles are summarized in Exhibit A of this paper, “Impact Innovation for Medical Devices: A Decision-Making Framework.” The framework includes a series of questions and tools for understanding a health equity problem and who it affects, evaluating the market and the viability of market entry, and assessing the minimum requirements for medical product sales.
The Rarity of Reverse, Frugal, and Impact Innovations for Medical Devices

The total number of successful reverse, frugal, and impact innovations for medical devices is quite small. That may be because the phenomenon of this kind of innovation is fairly new or because health products have specific barriers to market entry and scale. For example, medical devices in the United States must receive FDA approval, a process that is both costly and time consuming. Whereas, in low-income countries the bar to market entry for medical devices is much lower. Often there may not be a functioning regulatory agency or, if one does exist, it accepts the easier to obtain European Economic Area CE Mark.

Vijay Govindarajan, the author of Reverse Innovation, is the best source on the prevalence of reverse innovations. He has documented 25 full-fledged (i.e, poor to rich country) reverse innovations since 2009. Only two on his list are medical devices; and both—the portable ultrasound and the portable electrocardiogram—are GE products. In our interview with him, Govindarajan explained that his thinking about reverse innovation has evolved to include inventions that move not only from low- to high-income country (such as from India to the U.S.), but those that move between low-income countries (such as from India to Bangladesh). Thus his definition of reverse innovation is now not so different from frugal innovation.

Nonetheless, Govindarajan makes distinctions. He sees reverse innovation as moving in three stages: Stage 1–innovate in poor country; Stage 2–bring the innovation from one poor country to another; and Stage 3–bring the innovation to rich country. He said he would count products like D-Rev’s ReMotion Knee and its Brilliance phototherapy device as reverse innovations, even though neither product is available in high-income markets. He argued that the best way to do reverse innovation is by coming up with a product or service that can be developed and distributed in a “parallel” rather than a “sequential” fashion. “That means you’re looking at the whole world and saying, ‘How do I create a product for the whole world starting with India?’”* He pointed out, however, that sequential reverse innovation remains the more typical approach.

7Vijay Govindarajan’s May 28, 2015 list of reverse innovations shared on September 13, 2015.
8Phone interview with Vijay Govindarajan, September 3, 2015.
This is because designing goods and services, and especially medical products, that can serve customers’ needs in multiple markets and cultures is extremely difficult—even when assembling the best minds. Daniel Grossman, senior director of global health innovation at Medtronic and an emergency medicine physician at the Mayo Clinic, recounted to us that Medtronic, one of the world’s largest medical technology development companies, is just not designed to come up with reverse innovations.

“The way Medtronic functions,” he said, “is to employ U.S.-based engineers who are focused on markets like the U.S. market. They have historically not been asked to look at product design for low-resource settings or to understand how an Indian physician would use a device. So to say: Now think about these things from that point of view is a pretty big transition. It takes a different mindset, a global mindset, and it requires a lot of on-the-ground time.” Grossman is among many people who argue that reverse innovation for medical products is best achieved within small, independent teams in well-capitalized companies or startups.

If one looks at frugal innovation of medical devices—i.e., those that do not boomerang back to high-income markets—the phenomenon is more common. One example that has been getting attention is CellScope, a low-cost device that turns a smartphone into a high-powered diagnostic microscope. Developed over the past eight years at the Fletcher Lab at UC Berkeley, CellScope is now being tested on 60,000 river blindness patients in Cameroon and 2,000 tuberculosis patients in Vietnam. It could have a radical effect on tropical disease diagnosis and treatment, because the device can accomplish both, in rural settings, and without highly trained medical practitioners.10

International business consultants like Navi Radjou see frugal innovation as part of a widening phenomenon that involves multiple stakeholders from multiple countries. “We are really at an Age of Convergence,” said Radjou. “There are no first world problems and third world problems,” he explained, citing the effects of low water supplies on India and California and the explosion of chronic diseases worldwide. Radjou believes that co-creation of innovations is becoming the norm, because many innovations from emerging markets—especially the most celebrated ones from companies like Siemens, Phillips, and Renault—are created by teams of engineers and business strategists from countries like India, China, the U.S., and France.

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10 http://cellscope.berkeley.edu/
11 Phone interview with Navi Radjou, September 21, 2015.
This kind of international teamwork is also typical among startups like D-Rev, Embrace, and GRIT, whose innovations are covered in the following pages. In these cases, small US-based teams worked with partners in target markets. For example, the ReMotion Knee started as partnership between India’s Jaipur Foot Clinic and Stanford University before it was acquired by D-Rev. The D-Rev team built relationships with clinics in three additional countries—Guatemala, Indonesia, Ecuador—to test three iterations before the final design of the ReMotion Knee launched globally in December 2015.

To better understand the prevalence of reverse, frugal, and impact innovations for medical devices, it is crucial to understand not just this notion of international expertise integration—but such details as organizational model, R&D costs, and technical and business development processes. In the following pages, we will delve into these issues by examining one fully realized reverse innovation by one of the largest multinational companies in the world and three examples of medical device innovations developed by small product design organizations.

Design and Dissemination Processes in Reverse, Frugal, and Impact Innovation

The Vscan—a $10,000 portable ultrasound that GE introduced in 2009 with similar power and image quality as its $250,000 device—is one of the most lauded examples of a fully realized reverse innovation. As of September 2014, 15,000 Vscans had been sold in 100 countries. Yet the device did not cleanly reverse directions from low-income to high-income markets. According to Ajay Parkhe, GE Healthcare’s general manager of primary care ultrasound, the Vscan was seen as a medical device with global sales potential from a fairly early engineering phase.

Parkhe said that the decision to sell the portable ultrasound to across different markets happened in the new product introduction phase. And the R&D team, although based in Wuxi, China, included early stage expertise from 15 to 20 GE engineers and business professionals from Norway and other Western countries. He explained that step one for the team in China was to assess both the met and unmet needs in the marketplace. Step two was to start asking the technological questions that could fulfill those needs. “You read some of the publications that come out of the business press,” said Parkhe, “and they don’t address these nuances of product launch questions.”

13 Phone interview with Ajay Parkhe and Arvind Gopalratnam, August 3, 2015.
Vscan is a great example of a parallel market innovation. The Vscan team worked with patients and clinicians in China and India to drive the design of an ultrasound that could be affordable, easy to use, portable, and high quality for lower income consumers. Once the product was in development, however GE employees understood the Vscan was just as useful for small clinics or mobile medical situations (such as ambulances) in the U.S., and began to think of country-specific product adaptations. In essence, GE identified a new market segment: customers who previously would not have purchased the product. And the company did this without cannibalizing its more expensive ultrasound products, a key concern among medical device manufacturers.

In addition, although the Vscan team reduced the complexity and cost of previous ultrasound devices to sell it to previously overlooked consumers, the staffing and R&D resources behind the Vscan came from a multinational healthcare company with 2014 revenues of $18.3 billion and a global staff of thousands.\(^4\) GE is not exactly a lean startup, but it did show that an embedded startup in a large company could create a high-demand medical device for emerging markets.

Most importantly, GE’s global footprint allowed the company to take the strengths of each site and configure the whole program. Also, GE’s reputation and resources made perhaps the hardest part of bringing emerging market medical devices to the U.S.—funding clinical trials and getting FDA approval—fairly easy.

Although the Vscan has started to help close some health inequities by getting the product into places where infant and maternal deaths are high—GE does not keep health impact metrics on this device; those numbers are kept by GE’s intergovernmental partners, such as the World Health Organization. Yet the Vscan should be considered an impact innovation. The device is serving low-income clinics and patients. GE has spent significant resources educating clinicians about ultrasound, and in 2015 started training clinicians in several resource-constrained countries in Africa and Southeast Asia to use an even lower cost device, called Vscan Access.

Parkhe said Vscan’s sales approach has worked because it is tailored to the needs of health practitioners in low-income markets, who would not have bought GE’s expensive, stationary devices: “If you look at traditional ultrasound in the developing world, it was all about image quality, reimbursement, high price point product,” he said. “If you go in with that mindset, you will never come up with Vscan.”

Between 2005 and 2011, Amos Winter, an assistant professor in the Department of Mechanical Engineering at MIT, designed an off-road wheelchair for handicapped people in low-income countries called the Leveraged Freedom Chair (LFC).15 Winter describes the chair as 80 percent faster and 40 percent more efficient than a conventional wheelchair, yet priced at $250 when ordered in volumes of 100 or more. This price is on par with other low-income market wheelchairs and less than one twentieth the price of off-road wheelchairs available in wealthy countries.

Winter said these performance and price goals were accomplished because the LFC team came to realize: 1) that typical low-income market wheelchairs were tough to push on village roads and exhausting to propel long distances; 2) that imported wheelchairs were difficult to repair; and 3) that any solution would have to fit into the existing funding and distribution systems used for other low-income market wheelchairs.

The LFC team aimed to create a wheelchair that travels three miles a day over varied terrain, is usable and maneuverable indoors, and can be easily repaired locally and at low-cost. Perhaps the team’s greatest engineering insight was to create a means of changing mechanical advantage when propelling the chair, for traversing difficult terrain and controlling speed, by pushing on a pair of levers. Those levers make the wheelchair user both the power source and the gearbox of the wheelchair by simply changing his or her hand position on the levers to vary leverage and change gears. The other big insight was to use readily available parts from bicycles to construct the wheelchair. The LFC team formed partnerships with wheelchair users and builders throughout the low-income regions, and conducted field trials in East Africa, Guatemala, and India. Results from these tests helped refine the device to be smaller, lighter, and more nimble.

To date, Global Research Innovation & Technology (GRIT), the company that commercialized the LFC, has sold over 1,500 chairs to NGOs and aid organizations working in 17 low-income countries. The LFC has been distributed as far as Easter Island. It is a great example of a technology-for-development initiative funded by a research university. Winter said he was not able to estimate R&D costs, because they are bound up in various university supports, including free lab time, fellowships, innovation competitions, and free advice from faculty and design and manufacturing experts.¹⁶

¹⁶ Phone interview with Amos Winter and Tish Scolnik, August 28, 2015.
In 2012, Winter’s TED talk and positive press about the LFC led people in the U.S. to ask GRIT whether the wheelchair would come to America. To understand how the LFC should be modified to meet the needs wheelchair users in higher-income markets, the GRIT team conducted significant market research and designed the new Freedom Chair with two main adaptations: 1) ability to collapse and fit in the trunk of a car; and 2) quick release wheels that users can remove with one hand. The Freedom Chair uses modern bike parts found in American shops and is manufactured in Cambridge, MA.

The four-person team behind GRIT, lead by former MIT student Tish Scolnik, sells the Freedom Chair not as a medical product but as a recreational device for wheelchair users, calling it a “mountain bike for your arms.” GRIT launched the product through a November 2014 Kickstarter campaign, raising $79,072 from 374 backers and meeting their funding goal in five days.

The company began delivering Freedom Chairs in May 2015. Since then, it has sold about 70 chairs at $3,295 each. In 2015, GRIT raised its first round of investment; and according to Winter, the company shows promise of commercial sustainability. Although the Freedom Chair is not a wheelchair by definition, Winter and Scolnik argue it reduces health inequities because it gives people with disabilities the ability to go on hiking trails, dirt roads, etc. and gives them much-needed exercise and exposure to the great outdoors. However, the U.S. Freedom Chair would not be considered an impact innovation if the cost of the recreational device is too high to serve low-income patients.

Embrace was founded by a group of students at Stanford University’s Hasso Plattner Institute of Design in 2008, who were challenged to help families in the world’s poorest regions by inventing an infant warmer that costs less than 1 percent of the $20,000 incubators found in leading hospitals. As they designed their product, the Embrace team realized that the lack of highly skilled staff and continuous electricity needed to run traditional incubators and warmers was a larger challenge than cost. So they created an easy-to-use sleeping bag with a removable warming element, which heats up in 30 minutes using electricity or hot water.
Embrace was structured as a nonprofit in 2008, and received a variety of funding from innovation prizes, private foundations, and social enterprise fellowships. Yet the team recognized early on that to create impact and to scale faster, investments were needed for everything from product development and manufacturing to market entry and distribution. Thus in 2011, the organization created a for-profit social enterprise called Embrace Innovations, which received an undisclosed investment from Vinod Khosla’s Impact Fund and Jeff Skoll’s Capricorn Investment Group. The Embrace warmers, whose production began in 2011, cost about $300. According to the Oakland, Calif.-based nonprofit’s website, however, “the true costs involved in bringing the warmer to the infants who need it are much higher. We must also pay for screening, shipping, training, data collection, and ongoing support/maintenance.”

Raghu Dharmaraju, COO of Embrace Innovations, explained that the for-profit social enterprise handles the design, clinical testing, and manufacturing of the infant warmer device, as well as commercial sales to government and private hospitals that can afford to pay for a low-cost solution to hypothermia. The nonprofit, which merged with Thrive Networks in June 2016, runs maternal and infant health programs in the most challenging settings and donates the products as part of the programs. Together, Embrace and Embrace Innovations report they have helped more than 150,000 babies.

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18 Embrace Global website: http://embraceglobal.org
19 Phone interview with Raghu Dharmaraju, August 28, 2015.
In late 2015, Embrace Innovations also started selling a non-medical consumer product for the U.S. market called “Little Lotus.” Every Little Lotus sale—$150 for a pack of two infant sleeping bags—will fund one Embrace Nest or Embrace Care product. The Embrace Innovation team is thinking of this approach not so much as reverse innovation, but as a means to partly fund its social impact endeavors in emerging markets. Like GRIT’s Freedom Chair, the Little Lotus targets high-income costumers, not low-income patients. In the U.S. context, therefore, the product itself cannot be considered an impact innovation. Yet, the high sales price of the Little Lotus is a cross-subsidy model that creates impact in low-income counties.

In addition, although Embrace Innovation believes its technology can have applications in U.S. medical settings, it had decided against pursuing U.S. market entry and emerging market entry at the same time because it would mean a draw on cash and team bandwidth. Embrace’s primary work will be on impact innovations—those that target low-income countries that face significant challenges around maternal and infant health.

In 2008, a Stanford University class developed a high-performance, low-cost, prosthetic knee joint for above-knee amputees in collaboration with India’s Jaipur Foot Organization. Over the next six years, 7,400 patients in 15 countries were given a free JaipurKnee by the Jaipur Foot Organization.20

In 2010, the Jaipur-Stanford collaboration resulted in an improved version, called the ReMotion Knee. D-Rev acquired the ReMotion Knee and all related intellectual property a year later. In 2013, the nonprofit commenced field trials of ReMotion with 66 patients in India, Indonesia, and Guatemala. The ReMotion Knee—which differs from the JaipurKnee in that it was designed for high quality mass production and global sales—became available for sale at a retail cost of $80 in December 2015.

D-Rev expects that orders will come mostly from low-income countries, where amputees tend to have lost a limb due to a traumatic injury, such as a road accident. D-Rev also expects its target users will be young, active, and eager to go to school or return to work. As of September 2015, D-Rev has received 715 pre-orders from 17 countries.

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D-Rev is committed to making only impact innovations. Those products must fulfill three requirements: 1) products must be world-class (in other words, they must be as good as or better than similar products sold in high-income markets), 2) they must be user-obsessed (i.e., they must be made with users’ multiple needs and contexts in mind), and 3) they must be market-driven (D-Rev does not give away its products, because it believes world-class products can be designed affordably for any market). In her TED talk, D-Rev CEO Krista Donaldson stated that her nonprofit’s ReMotion knee performs significantly better than the $150 single-axis knee that the Red Cross gives away to amputees and on par with the $1,400 prosthetic knees sold in the United States.\(^2\) D-Rev has spent $1.5 million between 2009 and 2015 to engineer the device.\(^2\)

Shortly after Donaldson’s December 2013 TED talk, D-Rev began fielding calls from American prosthetists, amputees, and their family members interested to know if the ReMotion Knee would become available in the U.S. Over time, the nonprofit received more than 60 inquiries, including interest from Rob Pittman, a successful prosthetist and entrepreneur. As a result, the nonprofit started to seriously consider whether it should sell the ReMotion Knee in the United States, and began to research such issues as manufacturing, distribution, clinical trial costs, and unit cost. D-Rev thought the knee might become a reverse innovation—one that could serve low-income patients in India as well as the U.S. and make D-Rev financially sustainable.

\(^2\)Interview with Krista Donaldson, August 21, 2015, D-Rev offices in San Francisco, Calif.
In early 2015, D-Rev contracted with Harvard Business School Community Partners to perform a pro-bono U.S. market assessment to determine the ReMotion Knee’s 1) potential social impact, 2) barriers to market entry, 3) possibility for profit, and 4) possible business model. “The hope,” explained Donaldson, “was both to close health inequities in the U.S. and generate enough sales revenue to subsidize D-Rev’s future R&D of new products.” Based on early conversations with prosthetists, Donaldson and her team believed there could be a market for American amputees too poor to afford expensive knee replacements.

In June 2015, the Harvard group advised against U.S. market entry. It found that there was both a high degree of competition among American prosthetics manufacturers and a high degree of product differentiation, with knees of different degrees of stability and functionality selling from $350 to $1,500. D-Rev had estimated it could sell its product for about $300.

“While there appeared to be demand for our knee, we came to understand that market entry costs would be prohibitively high,” recounted Donaldson. D-Rev evaluated the product’s U.S. market cost against its potential social impact in low-income countries, and decided that the cost effectiveness there—and particularly the ability to close health inequities there—was much higher than what it could achieve in the U.S. In other words, the device could not serve as an impact innovation in America. In addition, despite interest in the ReMotion Knee from U.S. clinicians and foundations focused on improving U.S. health care, D-Rev encountered no one willing to support product development aimed at closing this U.S. health inequity gap.

“When it comes to reverse innovation, there seems to be an incentive to make more money by reducing cost of devices,” said Donaldson. “But there isn’t an incentive to pass on cost savings to patients or to reach patients who otherwise don’t have access to care. That’s why we feel the need to introduce the term ‘impact innovation.’ There needs to be a distinction between profitable innovations and socially impactful innovations.”

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Whom Do Reverse, Frugal, and Impact Innovations Benefit?

The question of who benefits from reverse and frugal innovation is rarely examined because the assumption—as propounded by business consultants and scholars—is that these innovations lead to increased revenues for developers and increased social impact for users and customers. Yet this assumption raises some problems for nonprofits and social enterprises, which place more importance on their social outcomes over profits—even ones that operate on market-based approaches. Those nonprofits and social enterprises need to use the term impact innovation to be clear that their primary goal is to reduce social inequities for low-income people.

Amos Winter of MIT and GRIT believes that “doing social good and making money are not mutually exclusive,” but said he could not think of any small organizations doing full-fledged reverse innovation. Winter noted that the startup culture for product design works well for serving low-income countries, but those startups don’t get acquired by large companies that could help scale products. Meanwhile, he said, multinational companies are acquiring startups that create products for rich countries, but this usually happens before the startup can adapt its products to poor countries. “There seems to be a stigma against technology created for developing countries,” said Winter. “Most U.S. companies don’t see these startups as a viable or investable businesses, despite the rapidly expanding field of impact investing.”

Raghu Dharmaraju of Embrace Innovations said that the nonprofit/for-profit structure of his organization has been instrumental in achieving social impact in a relatively short time. He said the for-profit social enterprise could not advance its technology and scale quickly enough without venture capital investment and revenues from sales. The Little Lotus infant sleeping bag, which is being launched in the U.S., is expected to result in significant sales revenue. On the other hand, without Embrace, the nonprofit, Dharmaraju believes his organization would have had to abandon or postpone a significant part of its social mission. “We would never have been able to reach places like Afghanistan and Mozambique,” said Dharmaraju, “if we didn’t have a nonprofit organization to work with closely.”
Krista Donaldson of D-Rev said her organization’s interest in developing a high quality, affordable product for the U.S was primarily to serve indigent patients as well as to build credibility in international markets where need is high. She said reverse innovation is commonly cited as lowering costs for consumers and increasing access for patients, but there isn’t a lot of clarity around the cost. “At D-Rev, we want to design impact innovations to serve health inequities,” she said. “But when we look at the cost of serving health inequities in the U.S., it’s much higher than in low-income countries, so it is prohibitive in terms of our resources and our mission.” AJ Viola, who directs D-Rev’s operations and strategy, commented: “In the U.S. medical sector, there’s not a big push to save money on medical devices. Savings of a couple hundred dollars or a couple thousand dollars are insignificant to purchasers, whereas in the places we work, these cost savings can make a huge difference in someone’s life.”

The promises of reverse innovation for medical products seem to work best for multinational companies like GE Healthcare, which have large capital and staff resources, a team of lawyers, a longstanding relationship with the FDA, brand name recognition in the American medical product market, and the will to create startups within their companies. Those factors have made it possible for Vscan to reduce health inequities and to serve as a reverse innovation that is also an impact innovation.

Small, nonprofit organizations like GRIT, Embrace, and D-Rev have been able to create impact innovations for low-income countries, but they have not been able to accomplish them for high-income countries. This is partly because philanthropies have little interest in investing in U.S. medical products. This does not mean that multi-market impact innovation of medical products among nonprofit startups is impossible. But, to date, there are no good examples of the phenomenon.

There is, however, much potential for impact innovations that can be transferred within low-income countries and to high-income countries, to close health inequities for the world’s poor.
Impact Innovation for Medical Products: Opportunities and Challenges

Among the most positive benefits of the term reverse innovation is the way it has shifted mindsets. No longer do scholars, businesspeople, nonprofit professionals, or funders question whether valuable products and services can be created in emerging markets for consumption in poor or rich countries. Yet the conversation about such innovations has focused mostly on technology transfer. To achieve further progress, there needs to be more focus on users and needs—what is variously called “design thinking” or “human-centered design.” There also needs to be more focus on closing social inequities.

Daniel Grossman of Medtronic, who has been following the reverse innovation phenomenon for a number of years, said to create valuable medical products for multiple markets and close health inequities, “It’s all about the on-the-ground time. And the more intense and the more specific you are about your on-the-ground research, the better your outcomes are going to be—not only from a product design standpoint but from a business model component as well.”

Grossman said the three main requirements for creating medical devices that close health inequities are: 1) engineers who can investigate problems in-country and design solutions for low-income users; 2) passionate leadership who will look beyond current market dynamics and foresee future needs; and 3) sound marketing of medical products. For the latter, he too cited the example of GE Healthcare, which recently created the training and education required to use the Vscan portable ultrasound in developing country clinics. “GE is going back and creating the care continuum component of the Vscan, so it can be used well in many places. That’s something they skipped initially and it’s something you have to do right off the bat,” said Grossman.

Startups like GRIT, Embrace, and D-Rev have managed to close health inequities in low-income countries by deploying the kinds of engineers and leadership Grossman describes. (In fact, for all three organizations, the engineers are the leadership, serving as both the makers and the CEOs.) With targeted funding, the impact of these startups could be greater across all economies and users. But the road to social impact and financial sustainability is rocky. Organizations that privilege financial sustainability can quickly sacrifice social impact, especially in serving low-income people. Organizations that privilege social impact over financial sustainability can easily go under.
There are real opportunities for funders that want to help the world’s poor through well designed, lifesaving medical devices. Amazingly, in the age of rapid innovation and cost reduction of health care products, there are no incentives for medical device organizations serving low-income customers to overcome market and structural barriers. One possibility is for multinational companies to provide funds or other incentives through their corporate social responsibility units. Another possibility would be for impact investors to decide that such medical devices are worth their attention and funds. A third possibility would be for foundations to provide R&D grants for devices that have the promise of scale—to low-income users in all geographies.

In either case, there needs to be a broader understanding of the challenges of reverse, frugal, and impact innovations for medical devices. And that understanding must come from engineers and products developers of social impact organizations as well as from business scholars and consultants of multinational companies.
References


Amos Winter, Jake Childs, and Jung Tak, "Case Study: Leverage Freedom Chair by: Enabling Freedom for the Disabled in Developing Countries," Core 77, February 6, 2011.


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D-Rev
IMPACT INNOVATION FOR MEDICAL DEVICES: A Decision-Making Framework

This set of questions is intended to help organizations evaluate if a health technology designed originally for use in a low-income market has the potential to transition to a higher-income country like the United States. Our focus with this work is to close health inequities, and our goal is to equip entrepreneurs with the technical, design and business tools and knowledge to address market introduction hurdles.

SECTION I: The Problem and Who it Affects
Use this section to understand the problem your product addresses, the scope of the problem and the key players who will influence your success.

I. PROBLEM
Understanding and Defining

a) What problem(s) are you solving?
b) Who is this a problem for? For example, is it a problem for a business, an intermediary, or a consumer?
c) What is the desired outcome of using your product?
d) Is the problem you’re solving in a low-resource market actually a problem in the U.S.?

TOOL-TO-USE

Stanford University’s Biodesign Need Statement
See examples of need statements and their development on the website for the textbook Biodesign: The Process of Innovating Medical Technologies.

“A way to address problem in population that outcome”
SECTION I: The Problem and Who it Affects

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II. USERS

Segmenting and Understanding Their Needs

a) Who are the target users? Who are all the customers?

b) Are there different segments of users who might take advantage of a solution? How do they differ from each other?

c) How does each user or stakeholder address the problem?

Example

ReMotion Knee user evaluation: The ReMotion Knee’s target user in India and other low-income countries tends to be young and active. This type of amputee has lost a limb due to traumatic injury and is often eager to be fit with a prosthesis to return to “normal” life.

In the US, however, low-income patients tend to be older and inactive. Their amputations resulted from disease and other poor health causes. If a designer were starting with these user needs to develop prostheses, he or she would likely design two different knees.

TOOL-TO-USE

Customer Value Chain Analysis

A visually mapping tool that indicates how customers or stakeholders are related to each other and what they value. The mapping of the customers enables designers to fully consider the range of user needs and requirements, as well as a structure to make tradeoffs during product development.
SECTION II: Market
Use this section to evaluate the U.S. market and the viability of market entry.

III. PRODUCT OFFERING
Defining Requirements and Expectations

a) Will the product need to have different features or functionality for entry into the higher income market? How much will that cost?
b) What additional requirements or support will be needed for market entry?
c) Are there expected norms of the product’s features, presentation, and support in your second market?
d) Will one product address the needs of all market segments or users groups?

Example

With Cellscope, a smartphone-compatible otoscope, the original intent was to provide health care diagnosis for populations that might not otherwise have access to ear, nose, and throat specialty care. In the U.S., according to ENT specialists, the Cellscope Otoscope is largely aimed at parents of children with frequent health problems, a different target user and use scenario.

TOOL-TO-USE

Landscape Analysis

Landscape analysis is research and review of other products and concepts that fully or partially address the defined problem. By understand the landscape of solutions, designers can also understand the rationale and expectations of target users and stakeholders. In Biodesign this is also called “existing solutions.”
SECTION II: Market

Use this section to evaluate the U.S. market and the viability of market entry.

IV. MARKET SIZE

Understanding the Opportunity for Impact

a) What is the size of the market? How is it segmented?
b) If you have different segments, will you need different market entry strategies?
c) Will your product meet the needs of all segments?
d) What portion of the market will you need to capture to have your intended impact?

TOOL-TO-USE

Market Sizing and Demand Forecasting

Market sizing aims to calculate the total number of users who could benefit from a product as well as the portion of those users who would actually be able and willing to purchase such a product. Standard approaches include “top-down” or estimating need based on macro factors (e.g., the number of premature babies born in the US), and “bottom-up” or estimating need based on the smallest unit of measure available (e.g., the number of hospitals in the US with neonatal intensive care units). There are myriad ways to approach these calculations—the U.S. Small Business Association provides some general guidance useful to those inexperienced in the area.

Effective tools distinguish between the overall need for a product and the actual demand for a product based on infrastructure and ability to pay. The Bill and Melinda Gates Foundation’s Demand Forecasting Tool is a comprehensive document that walks through these exercises in detail using vaccines, prevention diagnostics, and other medical products.
SECTION II: Market
Use this section to evaluate the U.S. market and the viability of market entry.

V. SALES & MARKETING
Reaching Users and Markets

a) What are the existing purchasing paths for similar products?
b) How do purchasing decision makers learn about new products?
c) What kind of sales force is required to generate product sales?
d) Do medical professionals need to see documented research or clinical trials?
e) How important is brand reputation in the category?

TOOL-TO-USE
Customer Segmentation Tool
This table from USAID’s Center for Accelerating Innovation and Impact prompts the entrepreneur to look at each customer group or segment, and consider their motivations in using the product, as well as how to best reach them.
SECTION II: Market

Use this section to evaluate the U.S. market and the viability of market entry.

VI. COMPETITION

Anticipating a Reaction

a) What and who is your competition?
b) How have those competitors changed over time?
c) Can you differentiate your product from competitive products in any area besides price?
d) How well-resourced are your competitors?
e) How important is the U.S. market to your competitors?

TOOL-TO-USE

Porter’s Five Forces

This is a classic framework for considering all aspects that influence profitability in an industry, from the power of suppliers to the threat of new entrants. This video provides a good summary to guide your thinking around the five forces.
SECTION III: Structural

Use this section to assess the minimum requirements for product sales in the U.S.

VII. REGULATORY REQUIREMENTS

Meeting Federal Requirements

a) What certifications and registrations are required to sell product in the U.S. market?
b) How much do required registrations cost, and how long does the certification process take?
c) How will registration costs affect the affordability of your product?

TOOL-TO-USE

Is Your Product Regulated?

The FDA provides a series of webpages that asks questions to help you classify your device. This is a good first step in understanding what regulatory requirements you will need to meet. While device classes vary by country they overlap more than they differ.

VIII. LIABILITY INSURANCE AND INTELLECTUAL PROPERTY

Managing Risk

a) What kind of liability insurance do you need in the U.S. market?
b) How does the cost compare to revenue and impact?
c) Will introducing your product provoke intellectual property litigation from competitors?
d) How will the costs of liability insurance and IP filings affect affordability of the product?

Example

The nonprofit Gradian Health found that liability insurance for its affordable Universal Anesthesia was relatively affordable compared to U.S. markets where costs were higher due to the greater likelihood of litigation.

TOOL-TO-USE

None. Talk to industry experts and do your research—many companies provide liability insurance. You will need legal expertise to perform the intellectual property analysis. Nonprofits can often access these resources on a pro-bono basis.
IX. DISTRIBUTION
Putting Products in People’s Hands

a) How are these products distributed in the U.S.? Directly or through 3rd party distributors?

b) Which distribution approach best reaches underserved populations?

c) How does a decision about your distribution model affect the affordability of the product?

d) What incentives must you provide to convince distributors to carry your product?

e) How important are existing relations between distributors and other manufacturers?

TOOL-TO-USE

Distributor Landscape Analysis

This is a modification of USAID’s Center of Accelerating Innovation and Impact’s Manufacturing Landscape Analysis: Using your customer value chain, focus in on how the product reaches your target buyers. Conduct due diligence to evaluate the companies and their offerings.
SECTION III: Structural
Use this section to assess the minimum requirements for product sales in the U.S.

**TOOL-TO-USE**

Physician Fee Schedule Search
Practitioners evaluate your product on the reimburse-ability. Reimbursement codes, unfortunately, tend to be siloed by specialty and there is not an all-encompassing tool. This is one of the reasons why US medical device companies like Medtronic produce clear reimbursement guides for their products. As a starter reference, we recommend: [Physician Fee Schedule Search](#) from the U.S. Centers for Medicare and Medicaid Services (CMS).
I. Sanford Biodesign Need Statement

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II. Customer Value Chain Analysis

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IX. Distributer Landscape Analysis

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X. Physician Fee Schedule Search

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